

Appl. No. : 09/582,817
Filed : November 8, 2000

SUMMARY OF INTERVIEW

Exhibits and/or Demonstrations

The inventor, Nathalie Zammatteo presented a demonstration of three different discs which had both binary data and an array which can be read by a reading device, which she also presented. From the demonstration it was apparent that the reading of the assay spots of the array is limited to specific areas of defined shape/surface area. In that embodiment, the registered data was on the bottom surface of the disc – as on the ordinary CD with pits and grooves. The array was located on the top surface of the disc. Ms. Zammatteo opened the reading device to demonstrate that it had two readers: the bottom one was a conventional CD reader for reading of the registered binary data, and the top one comprised a laser connected to a motor and a photodiode for reading of the assay spots of the array.

Identification of Claims Discussed

Claim 30

Identification of Prior Art Discussed

None

Proposed Amendments

The Applicants proposed limiting the claims to nucleic acids being bound to the surface, and that the nucleic acids are located in a region of the disc that is void of any tracks or grooves with registered data.

Principal Arguments and Other Matters

The Applicants argued that Claim 30 is fully enabled by the Specification as filed.

Results of Interview

The Examiner has agreed to consider the proposed claim amendments in view of the arguments, demonstration of the BioCD and the BioCD reader, and support in Figures 4 and 5 and Specification as filed at page 18, lines 9-11.

Applicant agreed to amend the Specification to include Brief Description of the Drawings.

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REMARKS

Applicant wishes to thank the Examiner for the courtesy extended to the Applicant representatives Daniel Altman and Daniel Hart and to one of the inventors, Nathalie Zammateo, by granting a personal interview. As a result of an agreement that was reached at the Interview on June 14, 2006, the Specification has been amended to add "Brief Description of the Drawings" and to correct typographical errors by way of submitting a Substitute Specification. Support for the introduced "Brief Description of the Drawings" can be found in the Specification (paragraphs [0026], [0080], [0090] [0106], and [0112] of the Substitute Specification). Claim 30 has been amended. Amendments to Claim 30 are supported in the Figures 4 and 5 and in paragraphs [0019], [0026], [0028], [0040], [0071], and [0080] of the Substitute Specification. Claim 31 has been cancelled as redundant. Therefore, no new matter has been introduced by these amendments. The following addresses the substance of the Office Action.

Specification

The Examiner has objected to the Specification for reciting various informal terms, such as "lecture" "safety constraint legislations", "convoyed", etc. During the interview the Examiner requested that a "Brief Description of the Drawings" be inserted into the Specification. Applicant has introduced the requested amendments and corrections by submitting the Substitute Specification. The marked-up version of the Substitute Specification shows the corrections made.

The Examiner has requested to provide the exact support for the limitation introduced in Claim 30 "microchannels are not grooves", or to amend Claim 30 accordingly. Claim 30 has been amended accordingly.

Enablement

The Examiner has maintained the rejection of Claims 30, 31, 34, 40, 41, 45 and 64 under 35 USC §112, first paragraph as allegedly non-enabled. Specifically, the claims were found not enabled for the detection of any target molecule where the binding does not take place in the pits found in the grooves. The claims were also found non-enabled for a device that comprises two different reading devices.

However, Figures 4 and 5 and paragraph [0071] provide enabling description of the disc where nucleic acids are located in a region of the disc that is void of any tracks or grooves with

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registered data. The same figures also show that the registered data from the CD track is read by one laser-based device, while the data from the array having nucleic acids is read by a separate reading device. Furthermore, during the course of the interview, the inventor had demonstrated a device for reading of a BioCD having the registered data on the bottom surface of the disc – as on the ordinary CD with pits and grooves, and the array located on the top surface of the disc. The reader was shown to have two reading devices: the bottom one was an ordinary CD-reading device for reading the registered data, while the top one was similar to OHP for reading the information from the array. The Examiner appreciated the presentation.

In addition, during the interview the Examiner noted that the claims recite that the capture molecules are nucleic acids. According to the Examiner, the claims encompass methods in which the capture molecules are ESTs of no known utility. As suggested by the Examiner during the interview, Applicants note that the presence of inoperable embodiments within the scope of a claim does not necessarily render a claim non-enabled. M.P.E.P. §2164.08(b). Furthermore, “‘[i]t is not a function of the claims to specifically exclude ... possible inoperative substances ...’”, unless the number of inoperative combinations becomes significant and requires a person having ordinary skill in the art to experiment unduly in order to practice the invention. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577 (Fed. Cir. 1984) (quoting *In re Dinh-Nguyen*, 492 F.2d 856, 858-859 (CCPA 1974).

With respect to the present application, the specification enables one to practice the claimed methods using discs having a large number of useful nucleic acid capture probes bound thereto. In fact, because the methodology for binding the nucleic acid capture molecules to the disc is independent of the sequence of the capture molecules, the claimed invention can be utilized with countless numbers of useful sequences. Uncharacterized ESTs of no utility do not represent such a significant portion of the nucleic acid capture molecules encompassed by the claimed methods to render the specification non-enabling, particularly in view of the fact that one skilled in the art would have no motivation to bind a useless nucleic acid capture molecule to the disc.

In addition, a claim is enabled so long as a person with skill in the art would be able to determine, without undue experimentation, which species within the scope of the claim would work and which would not. *In re Angstadt*, 537 F.2d 498, 503-05 (C.C.P.A. 1976). In the

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present situation, the manufacturer of the disc and the user of the disc know the identities of the nucleic acid capture molecules which are bound to the disc and the locations at which each of the nucleic acid capture molecules are bound. Thus, the manufacturers and users would know if any completely uncharacterized ESTs were fixed to the surface of the disc.

Finally, just as a description of a protocol for fixing a nucleic acid probe to nitrocellulose and hybridizing the fixed probe to a target nucleic acid enables one skilled in the art to perform a Southern blot even though uncharacterized ESTs are included among the many nucleic acids which could be fixed to the nitrocellulose using the Southern blot procedure, the description in the present specification of binding a nucleic acid capture molecule to a disc and hybridizing the capture molecule to a target nucleic acid enables one skilled in the art to practice the claimed invention even though the one could use the procedures in the specification with uncharacterized ESTs.

Double Patenting

The Patent Office rejected Claims 30, 31, 34, 40, 41, 45 and 64 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of co-pending Application No. 10/035,822. Under MPEP 804 II B "Nonstatutory Double Patenting," obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent. A rejection based on a nonstatutory type of double patenting can be avoided by filing a terminal disclaimer in the application in which the rejection is made. The filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection under *Quad Environmental Technologies Corp. v. Union Sanitary District*, 20 USPQ2d 1392 (Fed. Cir. 1991). The filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection. With respect to this rejection, Applicants respectfully submit that they will defer the filing of any terminal disclaimer until the rejected claims are otherwise indicated to be in condition for allowance.

The Patent Office has found Claims 30-34, 40, 41, 45 49 and 51-64 conflicting with claims 1-45, 48 and 50-88 of co-pending Application No. 10/035,822, and requested cancellation of the conflicting claims from all but one application or maintain a clear line of demarcation

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between the applications as required by MPEP §822. The Examiner is respectfully invited to call the undersigned to discuss the raised issues of double patenting.

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CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, Applicants request the expeditious allowance of the pending claims. The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the undersigned to discuss such issues.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: July 27, 2006

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